

April 11, 2019

Via Email and Federal Express

Mr. Vaughn Noga
Deputy Assistant Administrator for Environmental
Information and Chief Information Officer
United States Environmental Protection Agency
Washington, DC 20460

**Re Request for Reconsideration
#17002A Concerning Toxicological Review of Chloroprene
Our File: 165671-00**

Dear Mr. Noga:

In your letter of February 12, 2019, to Mr. Patrick Walsh with Denka Performance Elastomer LLC (DPE), EPA acknowledged DPE's submittal on February 1, 2019, of additional information supporting DPE's Request for Reconsideration (RFR) #17002A and Request for Correction (RFC) #17002 of the 2010 Toxicological Review of Chloroprene (CAS No. 126-99-8) (referred to herein as "the 2010 Toxicological Review"). In your February 12 letter, you also gave DPE until May 1, 2019, to submit additional information in support of its RFR and RFC. By this letter, DPE respectfully requests a one-month extension of the May 1 due date, or until June 3, 2019 (June 1 is a Saturday). The basis of this request for extension is set out below.

A critical component of DPE's RFC and RFR concerns the validity of the Inhalation Unit Risk (IUR) for the potential human carcinogenic response to chloroprene as contained in the 2010 Toxicological Review. As the Agency is aware, DPE and its scientists with the Ramboll consulting firm are working with EPA's National Center for Environmental Assessment (NCEA) to develop a Physiologically-Based Pharmacokinetic (PBPK) model for chloroprene. This ongoing effort and its importance for EPA's reconsideration of chloroprene are discussed on page 4 of the RFR. The purpose of the chloroprene PBPK model is to provide a technically sound basis to apply toxicological estimations derived from laboratory mice to humans. If a chloroprene PBPK model is developed that is acceptable to EPA, DPE expects that the PBPK model will be applied to re-calculate the chloroprene IUR contained in the 2010 Toxicological Review. The scientists with Ramboll predict that the new IUR based on the PBPK model could be approximately 68 times lower than the current IUR.

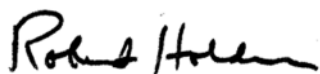
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In its submittal to EPA of February 1, 2019, DPE provided EPA with a PBPK model for chloroprene; however, as DPE noted at the time, DPE was also in the process of performing laboratory work with Teklab, Inc. (an EPA certified environmental laboratory), to measure a mass transfer coefficient ("K_g") for use in the PBPIK model. To complete the laboratory work according to the approved protocol, DPE facilitated the purchase of certain equipment and had it delivered to TekLab. This unexpected step delayed TekLab's ability to begin gathering the K_g data. Notwithstanding, we are pleased to advise you that Teklab has completed its laboratory work—however, we are still awaiting receipt of Teklab's final report. Although we are working with Ramboll to complete the K_g analyses and prepare an updated PBPK report by May 1 and will do everything in our power to meet that deadline, as a result of the delays associated with the K_g study, we are concerned that we may need additional time.

Accordingly, in an abundance of caution, Ramboll's scientists have asked us to seek from EPA additional time to ensure the development of the best possible work product to submit to EPA. Specifically, Ramboll is working (1) to address the Teklab findings in their PBPK report, (2) to address more fully physiological differences between male and female mice as reflected in the PBPK modeling (a subject raised recently in conversations with NCEA staff), and (3) to allow time for further discussions between the Ramboll and the NCEA scientists prior to the submittal of the final PBPK report. DPE's goal is to submit a PBPK model report that represents a scientific consensus between DPE, Ramboll, and EPA on the chloroprene PBPK model. If this effort is successful, it will obviate the need for EPA to address the most critical issue raised in the RFC and RFR -- the validity of the chloroprene IUR in the 2010 Toxicological Review. Even if other issues remain, the development and application of scientifically sound PBPK model will sharply reduce the issues for review in the RFC and RFR.

For the foregoing reasons, DPE respectfully requests a one-month extension of the May 1 due date, that is, until June 3, 2019. We would appreciate your response as soon as possible. If you have any questions, please contact me at 504-582-8139 or bholden@joneswalker.com. Thank you for your attention to this.

Sincerely,



Robert E. Holden
Attorney for Denka Performance Elastomer LLC

cc: **All Via Email Only:**

Ms. Vincia Holloman, OEI
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